

Analysis showed that the article consisted essentially of sodium chloride, sodium sulfate, sodium bicarbonate, sodium carbonate, a fluorine compound, and a trace of an iron compound, dissolved in water. The total amount of dissolved matter was 2 percent. Samples taken from the two shipments were found to contain 52.2 and 60 parts, respectively, per million of fluorine.

The product in both shipments was alleged to be misbranded in that it would be dangerous to health when used in the dosage or with the frequency prescribed, recommended, and suggested in the labeling, namely, (one shipment) "Directions: From  $\frac{1}{2}$  to  $\frac{3}{4}$  of an ordinary glass before breakfast and before retiring"; (second shipment) "Natural Water," since it contained an excessive amount of fluorine.

Both lots were alleged to be misbranded further in that the labeling was misleading since it failed to reveal the fact that the article contained fluorine, a poisonous substance, which fact is material in the light of the representations made in the labeling and material with respect to consequences which might result from the use of the article under the conditions of use prescribed in the labeling and under such conditions of use as are customary or usual.

Both lots were alleged to be misbranded further in that the labeling did not bear adequate warnings against use by children, where its use might be dangerous to health or against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users. The shipment of September 5, 1940, was alleged to be misbranded further in that the following statements in the labeling, "Try Pachanga Water for the Relief of certain ailments of Stomach, Bowels, Liver, Kidney, etc." and "Chemical Analysis show that Pachanga Water contains many mineral ingredients in a combination which has proven remarkably beneficial for many ailments of the human system," borne on the bottle label, were false and misleading since the article would not be efficacious and beneficial in the treatment of such ailments. This shipment was alleged to be misbranded further in that the bottle label failed to bear an accurate statement of the quantity of the contents.

On May 26, 1941, a plea of guilty having been entered, the court imposed a fine of \$100 on count I and ordered that imposition of sentence be suspended on count II and that the defendant be placed on probation for 2 years.

**327. Misbranding of Pachanga Mineral Water. U. S. v. 59 Bottles of Pachanga Mineral Water. Default decree of condemnation and destruction. (F. D. C. No. 3568. Sample No. 31532-E.)**

This product contained fluorine. It would be dangerous to health when used as directed in the labeling, and it was not labeled to indicate the consequences that might result from its use.

On December 21, 1940, the United States attorney for the Eastern District of Michigan filed a libel against 59 bottles of Pachanga Mineral Water at Detroit, Mich., alleging that the article had been shipped in interstate commerce on or about November 25, 1940, by Dr. T. M. Lukovich from Elsinore, Calif.: and charging that it was misbranded. It was labeled in part: "Pachanga Mineral-Antacid-Laxative Natural Water Pachanga Mineral Well."

The article was alleged to be misbranded in that the statement "Mineral-Antacid-Laxative Natural Water" was false and misleading since the label failed to reveal the fact that the article contained fluorine, a poisonous substance.

It was alleged to be misbranded further in that the label failed to bear adequate warnings against use by children where its use might be dangerous to health and against unsafe dosage and methods and duration of administration in such manner and form as are necessary for the protection of users.

It was alleged to be misbranded further in that it was dangerous to health when used in the dosage or with the frequency or duration suggested in the labeling "Natural Water."

On January 9, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**328. Misbranding of Aspirol Tablets and headache tablets. U. S. v. 1,005 Bottles of Aspirol Tablets and 1,416 Bottles of Headache Tablets. Consent decree of condemnation. Aspirol Tablets ordered released under bond for re-labeling; headache tablets ordered destroyed. (F. D. C. Nos. 2222, 2223. Sample Nos. 15165-E, 15169-E.)**

The product Aspirol Tablets was labeled to indicate that it was an aspirin preparation; whereas it contained other physiologically active ingredients. Its label also failed to bear a statement of the quantity of acetophenetidin that it

contained. The headache tablets contained acetanilid and would be dangerous to health when used as directed, and the label failed to reveal the consequences which might result from their use.

On June 17, 1940, the United States attorney for the Southern District of Illinois filed a libel against 1,005 bottles of Aspirol Tablets and 1,416 bottles of headache tablets at Bloomington, Ill., alleging that the articles had been shipped in interstate commerce on or about July 3, 1939, and April 19, 1940, by the J. R. Watkins Co. from Winona, Minn.; and charging that they were misbranded.

The Aspirol Tablets were alleged to be misbranded in that the name was false and misleading because it was derived from the ingredient aspirin; whereas they contained other active ingredients, including acetophenetidin and caffeine citrate. They were alleged to be misbranded further in that they were fabricated from two or more ingredients and the label failed to bear a statement of the quantity of acetophenetidin contained in each tablet.

The Headache Tablets were alleged to be misbranded in that the statements in the labeling, "Headache \* \* \* If pain is severe take two tablets for first dose \* \* \* Directions: Adults: One tablet every 2 hours until relieved. Take no more than 4 tablets in 24 hours. Children: Over 10 (only) half dose," were false and misleading since they created the impression that the article constituted an appropriate treatment for headache; whereas it was not such a safe and appropriate remedy but was a dangerous drug, and the label failed to reveal the fact, material in the light of the representations made as quoted hereinbefore, that the use of the article in accordance with the directions might cause serious blood disturbances, anemia, collapse, or a dependence on the drug. It was alleged to be misbranded further in that it was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling.

On February 25, 1941, G. C. Heberling Bros., Bloomington, Ill., having appeared as claimant and having consented to the entry of a decree, judgment of condemnation was entered and it was ordered that the Aspirol Tablets be released under bond conditioned that they be properly relabeled under the supervision of the Food and Drug Administration and that the headache tablets be destroyed.

**329. Misbranding of Watkins Laxative Cold Tablets. U. S. v. 300 Boxes of Laxative Cold Tablets. Default decree of condemnation and destruction. (F. D. C. No. 2310. Sample No. 323-E.)**

This product would be dangerous to health when used as directed in the labeling and was not labeled to indicate the consequences that might result from its use. It was misbranded further because it was labeled to indicate that it was a safe and appropriate remedy for the conditions for which it was recommended and in the other respects referred to hereinafter.

On July 6, 1940, the United States attorney for the Western District of North Carolina filed a libel against 300 boxes of laxative cold tablets at Charlotte, N. C., alleging that the article had been shipped in interstate commerce on or about February 15, 1940, by the J. R. Watkins Co., from Newark, N. J.; and charging that it was misbranded.

Analysis showed that the article contained 1.9 grains of acetanilid (1.9 grains per tablet), total alkaloids including quinine and alkaloids of belladonna (0.25 grain per tablet), and extracts of plant drugs including a laxative drug.

The article was alleged to be misbranded in that the following statements (tin container) "Directions \* \* \* For Cold Symptoms. Adult Dose: Take two tablets every three hours until three doses have been taken. This should cause the bowels to move freely. Then take one tablet three times a day until all symptoms are removed. For Casual Headaches. Adult Dose: Two tablets to be followed by one every three hours when necessary (not exceeding 6 in 24 hours). If headaches persist or return frequently, consult your physician. For children. Over ten years of age one-half adult dose; over five years of age one-fourth adult dose," and (circular) "At The First \* \* \* Chill, Or Fever \* \* \* Take Watkins Laxative Cold Tablets \* \* \* Watkins Laxative Cold Tablets contain ingredients that are selected to be used to treat the symptoms of colds and headaches. Especially good for sneezing or nasal discharge, headache and other disagreeable symptoms usually associated with colds. They increase the action of the bowels. In this manner they help to carry off from the system waste substances that tend to keep up the headache